

WHAT IS CLAIMED IS:

1. A sensor for implantation in a body, the sensor comprising:
 - a substrate with notches cut in the substrate to form a necked down region in the substrate; and
 - 5 at least one sensor electrode formed from one or more conductive layers.
2. A sensor in accordance with claim 1, wherein the thickness of the substrate ranges from approximately 25μ to 350μ .
- 10 3. A sensor in accordance with claim 1, wherein the thickness of the substrate ranges from 5μ to 750μ .
4. A sensor assembly in accordance with claim 1; further including:
 - a slotted needle having a slot; and
 - 15 wherein the notches creating the necked down region that allows the substrate to slide into the slotted needle that has the slot narrow enough to permit passage of the necked down region, but prevents a non-necked down region of the substrate from pulling out of the slotted needle through the slot.
- 20 5. A sensor assembly in accordance with claim 4, wherein slot of the slotted needle permits the necked down region of the substrate to slide down the slot.
6. A sensor in accordance with claim 1, wherein a width of the substrate in the non-necked down portion is sized to fit within a slotted needle having a diameter smaller than 21 gauge.
- 25 7. A sensor in accordance with claim 6, wherein a width of the substrate in the non-necked down portion is sized to fit within a slotted needle having a diameter smaller than 22 gauge.
8. A sensor in accordance with claim 7, wherein a width of the substrate in the non-necked 30 down portion is sized to fit within a slotted needle having a diameter smaller than 23 gauge.

9. A sensor in accordance with claim 8, wherein a width of the substrate in the non-necked down portion is sized to fit within a slotted needle having a diameter smaller than 24 gauge.

5 10. A sensor in accordance with claim 1, wherein at least one of the at least one sensor electrode is formed on a first surface of the substrate.

11. A sensor in accordance with claim 10, wherein all of the at least one sensor electrode are only formed on the first surface.

10 12. A sensor in accordance with claim 10, wherein at least another one of the at least one sensor electrodes is formed on a second surface of the substrate.

15 13. A sensor in accordance with claim 12, wherein a third one of the at least one sensor electrode is a reference electrode configured to contact a skin surface.

14. A method of making a sensor comprising the steps of:

i) providing a preformed self-supporting flexible substrate;
ii) sputter-depositing at least one metal layer on the substrate;

20 iii) etching the at least one metal layer to form a sensor electrode having a proximal segment and a distal segment;

iv) plating a metal layer on the sensor electrode; and
v) separating the sensor electrode and at least a portion of the substrate underlying the sensor electrode from the remainder of the substrate.

25 15. The method of claim 14, wherein the substrate is comprised of a polymeric material.

16. The method of claim 15, wherein the polymeric material is a polyimide.

30 17. The method of claim 14, wherein in step i) the substrate is a continuous web.

18. The method of claim 14, wherein in step ii) a plurality of metal layers are sequentially sputter-deposited, and in step iv) the plated layer is formed on the uppermost sputter-deposited layer.

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19. The method of claim 18, wherein the plurality of metal layers are comprised of at least two different metal layers.

20. The method of claim 19, wherein the plurality of metal layers are layers of chromium and copper that are sequentially sputter-deposited.

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21. The method of claim 14, wherein prior to step ii) a layer of a material that promotes adhesion between the sputter-deposited metal layer and the substrate is deposited on the substrate.

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22. The method of claim 14, wherein in step iv) a layer of copper is plated on the sensor electrode.

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23. The method of claim 14, wherein in step iv) a plurality of layers are sequentially plated on the sensor electrode.

24. The method of claim 14, wherein in step iv) a layer of gold is plated on the sensor electrode.

25. 25. The method of claim 14, wherein in step iv) layers of copper and gold are sequentially plated on the sensor electrode.

26. The method of claim 14, wherein before step v) the sensor electrode is provided with a coating.

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27. The method of claim 26, wherein the coating comprises a polymeric material.

28. The method of claim 27, wherein the polymeric material is biocompatible.

5 29. The method of claim 27, wherein the polymeric material is selected from the group consisting of acrylates, polyimide, soldermasks, and epoxy acrylate copolymers.

30. The method of claim 26, wherein the coating is subsequently removed from at least one of the proximal segment and the distal segment of the sensor electrode.

10 31. The method of claim 30, wherein the coating is removed from both the proximal segment and the distal segment of the sensor electrode.

15 32. The method of claim 30, wherein the coating is removed from the distal segment of the sensor electrode and the distal segment is subsequently provided with an electrode chemistry.

33. The method of claim 32, wherein the sensor electrode is provided with a membrane after the distal segment thereof is provided with the electrode chemistry.

20 34. The method of claim 26, wherein a plurality of sprocket holes are formed in the substrate adjacent to the sensor electrode.

35. The method of claim 14, wherein the substrate has an upper surface on which the sensor electrode is formed and a lower surface, and wherein after step iv) a bead is formed on at least 25 one of the lower surface and the sensor electrode.

36. The method of claim 35, wherein the bead is formed below and in alignment with the sensor electrode.

37. The method of claim 35, wherein a first bead is formed on the lower surface of the substrate and a second bead is formed on the sensor electrode.

38. The method of claim 35, wherein the bead is formed using a liquid polymer.

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39. The method of claim 35, wherein the bead is formed by a molding process.

40. The method of claim 14, wherein step v) is carried out using a laser.

10 41. The method according to claim 14, wherein in step ii) a plurality of metal layers is sequentially sputter-deposited on the substrate, the plurality of layers including an uppermost layer, and a metal layer is plated on the uppermost sputter-deposited metal layer; wherein in step iii) the plated and sputter-deposited metal layers are etched to form the sensor electrode having the proximal segment and the distal segment; and wherein in step iv) sequentially plating first and second metal layers on the sensor electrode; and

15 further comprising between the steps iv) and v) the steps of:

- a) coating the sensor electrode with a polymeric material; and
- b) forming at least one opening in the coating.

20 42. The method of claim 41, wherein in step ii) layers of chromium and copper are sequentially sputter-deposited.

43. The method of claim 41, wherein in step ii) a layer of copper is plated.

25 44. The method of claim 41, wherein in step iv) layers of copper and gold are sequentially plated.

45. The method of claim 41, wherein in step vi) the polymeric material is a polyimide.

46. The method according to claim 14, wherein in step i) the substrate is provided having an upper surface and a lower surface, wherein in step ii) at least one metal layer is sputter-deposited on at least one surface of the substrate, wherein in step iii) the at least one metal layer is etched to form the sensor electrode to have first and second edges, and

5 further comprising a step z) forming a bead on at least one of the upper surface and the lower surface of the substrate.

47. The method of claim 46, wherein the substrate is comprised of a polymeric material.

10 48. The method of claim 47, wherein the polymeric material is a polyimide.

49. The method of claim 46, wherein in step i) the substrate is provided in the form of a tape supplied from a reel.

15 50. The method of claim 46, wherein in step i) the substrate is formed by a casting process.

51. The method of claim 46, wherein in step ii) a plurality of metal layers are sequentially deposited on the substrate.

20 52. The method of claim 51, wherein layers of chromium and copper are sequentially deposited on the substrate.

53. The method of claim 46, wherein in step z) the sensor electrode is formed on one of the upper and lower surfaces of the substrate and the bead is formed on the other surface of the
25 substrate.

54. The method of claim 53, wherein in step z) the bead is formed on the substrate beneath the sensor electrode.

55. The method of claim 54, wherein in step z) the bead is formed by

- a) forming a perforation in the substrate adjacent to the first and second edges of the sensor electrode;
- b) securing the lower surface of the substrate to a mold, the mold having defined therein a channel that extends beneath the sensor electrode;
- c) flowing a liquid polymer over the upper surface of the substrate and through the perforations therein into the channel until the polymer beads on the upper surface of the substrate and covers at least a portion of the sensor electrode;
- d) curing the liquid polymer; and
- e) removing the substrate from the mold.

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56. The method of claim 55, wherein in step z-a) the perforations on each side of the sensor electrode include at least one perforation gap, so that the liquid polymer that flows over the sensor electrode does not cover the portion of the sensor electrode between the perforation gaps.

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57. The method of claim 56, wherein the perforations on each side of the sensor electrode include a plurality of perforation gaps.

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58. The method of claim 57, wherein each perforation has a perforation gap adjacent to at least one of the proximal and distal segments of the sensor electrode.

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59. The method of claim 58, wherein each perforation has a perforation gap adjacent to both the proximal segment and the distal segment of the sensor electrode.

60. The method of claim 59, wherein the distal segment is provided with an electrode chemistry.

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61. The method of claim 46, wherein a first bead is formed on one surface of the substrate, a second bead is formed on the other surface of the substrate, and the sensor electrode is formed adjacent to at least one of the beads.

62. The method of claim 46, wherein at least one sensor electrode is formed on each surface of the substrate and a bead is formed on each surface of the substrate adjacent to the sensor electrode.

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63. The method of claim 46, wherein after step iii) at least one additional metal layer is formed on the sensor electrode.

64. The method of claim 46, wherein after step iii) a layer of gold is electroplated on the

10 sensor electrode.

65. The method of claim 46, wherein the step z) includes:

- a) forming a perforation in the substrate adjacent the first and second edges of the sensor electrode;
- b) securing the lower surface of the substrate to a mold, the mold having a channel that extends below the metal layer;
- c) flowing a liquid polymer over the upper surface of the substrate and through the perforations therein into the channel until the polymer covers the upper surface of the substrate and at least a portion of the sensor electrode;
- d) curing the liquid polymer; and
- e) removing the substrate from the mold; and

wherein step ix) includes removing the sensor electrode, the cured polymer and the portion of the substrate between the first and second perforations by separating the substrate adjacent to the perforations.

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66. The method of claim 65, wherein after step iii) at least one additional metal layer is formed on the sensor electrode.

67. The method of claim 66, wherein after step iii) a layer of gold is electroplated on the

30 sensor electrode.

68. The method of claim 66, wherein after step viii) the distal segment of the sensor electrode is provided with the electrode chemistry.

5 69. A method of making a sensor comprising the steps of:

- i) providing a substrate;
- ii) forming at least one sensor electrode on the substrate;
- iii) forming a bead on the substrate; and
- iv) separating the bead, the sensor electrode and at least a portion of the substrate

10 between the bead and the sensor electrode from the remainder of the substrate.

15 70. The method of claim 69, wherein in step i) the substrate is provided having an upper surface and a lower surface, wherein in step ii) at least one channel is formed in at least one of the upper and lower surfaces of the substrate, and a conductive material is disposed in the at least one channel to form the at least one sensor electrode, and wherein in step iii) a bead is formed on at least one of the upper and lower surfaces of the substrate.

20 71. The method of claim 69, wherein in step i) the substrate is provided having an upper surface and a lower surface, wherein in step ii) a conductive material is disposed on at least one of the upper and lower surfaces of the substrate by non-impact printing to form at least one electrode, and wherein in step iii) a bead is formed on at least one of the upper and lower surfaces of the substrate to produce a sensor.

25 72. The method of claim 69, wherein in step i) the substrate is provided having an upper surface and a lower surface, wherein in step ii) a film or sheet comprising a conductive material is provided, and the conductive material from the film or sheet is transferred to the substrate to form at least one sensor electrode, and wherein in step iii) a bead is formed on at least one of the upper and lower surfaces of the substrate.

30 73. A sensor produced by the method of claim 14.

74. A sensor set comprising:
a) a mounting base adapted for mounting onto a patient's skin;
b) a sensor as claimed in claim 73;
c) a cannula protruding from the mounting base and having a portion of the sensor;

5 and

d) an insertion needle carried by the mounting base to protrude from the mounting base and having at least a portion of the cannula nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side to permit sliding withdrawal of the 10 insertion needle from the mounting base and the nested portion of the cannula.

75. A sensor produced by the method of claim 41.

76. A sensor set comprising:

a) a mounting base adapted for mounting onto a patient's skin;
b) a sensor as claimed in claim 75;
c) a cannula protruding from the mounting base and having a portion of the sensor;

15 and

d) an insertion needle carried by the mounting base to protrude from the mounting 20 base and having at least a portion of the cannula nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side to permit sliding withdrawal of the insertion needle from the mounting base and the nested portion of the cannula.

77. A sensor produced by the method of claim 46.

78. A sensor set comprising:

- a) a mounting base adapted for mounting onto a patient's skin;
- b) a sensor as claimed in claim 77; and
- c) an insertion needle carried by the mounting base to protrude from the mounting

5 base and having at least a portion of the bead of the sensor nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side to permit sliding withdrawal of the insertion needle from the mounting base and the nested portion of the sensor.

79. A sensor produced by the method of claim 65.

10 80. A sensor set comprising:

- a) a mounting base adapted for mounting onto a patient's skin;
- b) a sensor as claimed in claim 79; and
- c) an insertion needle carried by the mounting base to protrude from the mounting

15 base and having at least a portion of the bead of the sensor nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side thereof to permit sliding withdrawal of the insertion needle from the mounting base and the nested portion of the sensor.

20 81. A sensor produced by the method of claim 70.

82. A sensor set comprising:

- a) a mounting base adapted for mounting onto a patient's skin;
- b) a sensor as claimed in claim 81; and
- c) an insertion needle carried by the mounting base to protrude from the mounting

25 base and having at least a portion of the bead of the sensor nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side to permit sliding withdrawal of the insertion needle from the mounting base and the nested portion of the sensor.

30 83. A sensor produced by the method of claim 71.

84. A sensor set comprising:

- a) a mounting base adapted for mounting onto a patient's skin;
- b) a sensor as claimed in claim 83; and
- c) an insertion needle carried by the mounting base to protrude from the mounting base and having at least a portion of the bead of the sensor nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side to permit sliding withdrawal of the insertion needle from the mounting base and the nested portion of the sensor.

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85. A sensor produced by the method of claim 71.

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86. A sensor set comprising:

- a) a mounting base adapted for mounting onto a patient's skin;
- b) a sensor as claimed in claim 85; and
- c) an insertion needle carried by the mounting base to protrude from the mounting base and having at least a portion of the bead of the sensor nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side thereof to permit sliding withdrawal of the insertion needle from the mounting base and the nested portion of the sensor.

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87. The method of claim 30, wherein an additional metal layer is applied to the sensor electrode where the coating was removed.

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88. The method of claim 41, wherein an additional metal layer is applied to the sensor electrode where the coating was removed.

89. A sensor set comprising:

- a) a mounting base adapted for mounting onto a patient's skin;
- b) a sensor as claimed in claim 1; and
- c) an insertion needle carried by the mounting base to protrude from the mounting base and having at least a portion of the sensor nested within the insertion needle, the insertion needle defining a longitudinally extending slot along one side to permit sliding withdrawal of the insertion needle from the mounting base and the nested portion of the sensor and to accept the necked down region of the substrate.

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